PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 4 : A61F 2/46, 2/30

A1

(11) International Publication Number: WO 86/ 06618

(43) International Publication Date: 20 November 1986 (20.11.86)

(21) International Application Number: PCT/EP85/00227

(22) International Filing Date: 14 May 1985 (14.05.85)

(71) Applicant *(for all designated States except US)*: LABOR FÜR EXPERIMENTELLE CHIRURGIE [CH/CH]; Schweizerisches Forschungsinstitut, Obere Strasse 22, CH-7270 Davos (CH).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)* : TEPIC, Slobodan [YU/CH]; Oberstrasse 55, CH-7270 Davos Platz (CH).

(74) Agent: LUSUARDI, Werther, G.; Lyss-Str. 12, CH-3293 Dotzigen (CH).

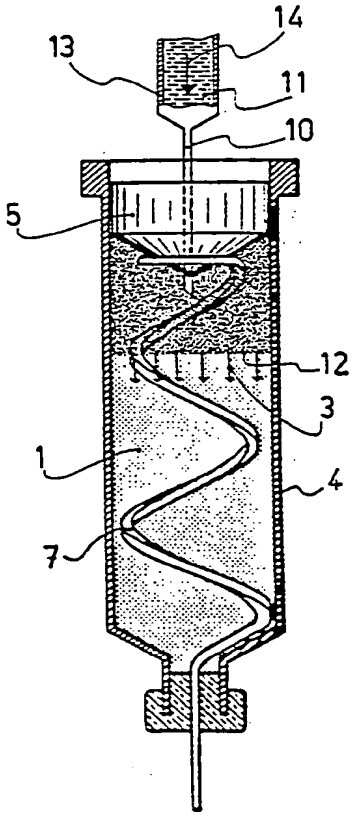
(81) Designated States: AT (European patent), BE (European patent), CH (European patent), DE (European patent), FR (European patent), GB (European patent), IT (European patent), LU (European patent), NL (European patent), SE (European patent), US.

Published
With international search report.

(54) Title: METHOD AND APPARATUS FOR PREPARAING A SELF-CURING TWO COMPONENT POWDER/ LIQUID CEMENT

(57) Abstract

The method of preparing a self curing two component powder liquid cement is particularly useful for the preparation of bone cement in orthopedics. The methods consists in flooding (3) the interspaces (2) between the powder component particles (1), said interspaces (2) being evacuated, with a polymerizable liquid component (11) and mechanically homogenizing the resulting cement mass (15) by means of the internal mixing device (7). The method is preferably performed in a syringe type container (4) whereby the liquid component (11) in the ampule (13) is injected through the piston (5) into the powder component (1).



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria
AU	Australia
BB	Barbados
BE	Belgium
BG	Bulgaria
BR	Brazil
CF	Central African Republic
CG	Congo
CH	Switzerland
CM	Cameroon
DE	Germany, Federal Republic of
DK	Denmark
FI	Finland
FR	France
GA	Gabon
GB	United Kingdom
HU	Hungary
IT	Italy
JP	Japan
KP	Democratic People's Republic of Korea
KR	Republic of Korea
LI	Liechtenstein
LK	Sri Lanka
LU	Luxembourg
MC	Monaco
MG	Madagascar
ML	Mali
MR	Mauritania
MW	Malawi
NL	Netherlands
NO	Norway
RO	Romania
SD	Sudan
SE	Sweden
SN	Senegal
SU	Soviet Union
TD	Chad
TG	Togo
US	United States of America

METHOD AND APPARATUS FOR PREPARING A SELF-CURING TWO COMPONENT POWDER/LIQUID CEMENT

This invention relates to a method and apparatus for preparing a cement composed of a powder and a liquid component which polymerize when brought into contact with each other. The invention is especially useful in connection with a cement which is used for medical purposes, particularly as bone cement or denture base material.

Background of the Invention

Many modern day bone cements of the two component powder/liquid type are known which, when thoroughly mixed together, undergo polymerization thereby forming a hard and more or less durable cement mass.

While the present invention can be used to prepare a variety of such cements, it is especially useful in the preparation of so-called bone cement used to anchor and

support artificial joint components and other prostheses in natural bone. Accordingly, it will be described here specifically in that context.

The currently preferred bone cement is polymethylmethacrylate or so-called PMMA. PMMA is comprised of a powdered polymer and a liquid monomer. Upon mixing, these components polymerize within minutes so as to form a firm rigid bond between the prosthesis and the surrounding bone structure in which the prosthesis is placed.

The present procedure for preparing PMMA bone cement is to thoroughly mix the powder and liquid component in order to start polymerization whereby the cement mass turns to a putty or dough consistency. The partially cured cement is then applied to the bone structure to be treated, e.g. into the medullary canal of the femur which is receiving a femoral shaft of a hip joint prosthesis.

All known methods for mixing bone cement have serious drawbacks, the most essential being:

- poor mixing, which depends on the individual mixing technique;
- high exotherm, due to the considerable amount of liquid component necessary to produce an applicable cement mass by conventional mixing techniques;
- creation of porosities by inclusion and entrapment of air bubbles as well as by evaporation of excess monomer resulting in significant degradation of the mechanical properties of the cured cement.

Summary of the Invention

Accordingly, the present invention aims to provide an improved method and apparatus for preparing a two component cement which is independent from the individual mixing technique.

Another object of the invention is to provide such a method which by its reduced amount of liquid component necessary to produce an applicable cement mass lowers considerably the maximum temperature reached during polymerization.

Still another object of the invention is to provide such a method which eliminates porosities in the cured cement by exclusion of air and by prevention of monomer evaporation.

Brief description of the drawing

In the drawing:

Fig. 1 is a perspective view of the powder component particles in a tightly packed state as used for the invention;

Fig. 2 is a sectional view of the syringe type container for the powder component used in the apparatus according to the invention;

Fig. 3 shows the liquid component injection through the piston of the syringe type container in a sectional view;

Fig. 4 shows the liquid component injection through the

plug of the syringe type container in a sectional view;

Fig. 5 is a sectional view of the syringe type container showing the internal mixing process step;

Fig. 6 is a sectional view of the syringe type container with an additional nozzle showing the extrusion process step;

Fig. 7 is a sectional view of the ampule used for the invention;

Fig. 8 is a diagram showing the dynamics of the flooding process of the invention.

Detailed description of the invention

As illustrated in Figure 1 the powdered component of the cement 1 is packed as tightly as possible in the container 4 (Figure 2) and the container is evacuated. Thus void space 2 contains no, or very little air. When allowed to enter the container 4, the liquid component will flood (arrow 3) void space 2 between the powder particles. This is the initial phase of the mixing process producing a powder-liquid mixture without any, or with very little air inclusion.

Figure 2 shows a pre-packaged powder component 1 in the container 4. Container 4 is of a syringe type with piston 5. The extrusion end 18 of the container is closed with a plug 6. An internal mixing device 7 protrudes through the plug 6 with its shaft 8. The container is evacuated in the packaging pro-

cess. For increased shelf life the outer package 9 is also evacuated and sealed. It may be made of aluminum foil for example. It may also serve as the sterile outer package.

Figure 3 shows the liquid component injection. This is done prior to application upon removal of the container 4 from the package 9. A needle 10 is inserted through the elastomer part of piston 5. Liquid component of the cement, which predominantly consists of methylmethacrylate 11 enters the container 4 and floods as indicated by arrows 3 the powder component particles 1. Flooding front 12 advances as described in more detail later (reference is made to Figure 8 description). Liquid component 11 may be ejected as indicated by arrow 14 from its container 13 either by a piston if 13 is a syringe, or simply sucked out by the vacuum in the container 4 if the container 13 is an ampule as shown in Figure 7.

Figure 4 shows the liquid injection through the plug 6 with the aid of the needle 10.

Figure 5 shows additional homogenization of the mixture 15 by means of the internal mixing device 7. Since flooding alone may not produce a mixture uniform enough for the critical medical applications such as bone cement, means for additional mechanical mixing is provided in that an axially collapsable mixing device 7 is enclosed and sealed within the container 4. It may be made of a suitable metal, or plastic.

Its shaft 8 protrudes through the plug 6 which ensures air tight seal of the container 4. The shaft 8 may be gripped in the chuck of say a power drill and turned as indicated by arrow 16. It may also be inserted in the specially provided mixer 17. The end of the shaft 8 may be adapted for simple coupling to the mixer 17. Time allowed for homogenization depends on the rate of the polymerization and is typically a few minutes. Since handling of the cement is minimized and no settling time is needed for air bubbles to come out of the mixture as it is the case in the conventional mixing, a major advantage of this procedure arises - mixing time may be increased many-fold. There is no monomer evaporation since the container 4 remains sealed throughout the injection and homogenization phases.

Figure 6 shows extrusion 21 of the cement following homogenization. For that a piston rod 20 is pushed in following removal of the plug 6. Extrusion may be done through the container end 18 or through an additional nozzle 19 attached to the container end 18.

Figure 7 shows a preferred embodiment of the liquid component container 13. It is in the form of a glass ampule. Narrowed end 22 is shaped so as to allow needle attachment onto the conus 24. The cap 25 is broken-off at the neck 26. The needle 10 is attached to the conus 24. The ampule is then turned upside-down and the needle 10 is inserted into the container

4 through either the piston 5 or the plug 6. The cap 28 on the other narrowed end 23 of the ampule 13 is then broken-off at the neck 27 allowing the liquid 11 to flood the powder component particles 1 in the container 4 as shown in Figures 3 and 4.

Figure 8 shows the dynamics of the flooding process, whereby pressure drop in the injection needle 10 is neglected. Flooding front 12 position x in the powder column 1 is proportional to the square root ot time. The constant of proportionality a depends on the powder column permeability, the liquid viscosity and the column cross-section. The front 12 will arrive to the end of the column x_c in finite time t_c and with finite speed.

Claims

1. The method of preparing a self curing two component powder liquid cement characterized in that the powder component containing a polymerization catalyst is evacuated at least partially and the interspaces (2) between the powder particles (1) are flooded with the liquid component (11) containing a polymerizable monomer, comonomer, prepolymer or mixtures thereof, thereby forming a polymerizable cement mass (15).

2. The method according to claim 1, characterized in that the polymerizable cement mass (15) is further homogenized by mechanical means (7), which preferably are collapsable.

3. The method according to claim 1 or 2, characterized in that the weight ratio of powder/liquid is between 3,6 and 2,4 , preferably between 3,6 and 3,0.

4. The method according to one of the claims 1 to 3, characterized in that it is carried out in a container (4),

preferably in form of a syringe, containing the evacuated powder (1) by introducing the liquid component (11) through the plug (6) or the piston (5) of the container (4).

5. The method according to one of the claims 1 to 4 characterized in that the powder component consists of particles (1) of approximately uniform size and preferably of approximately spherical form.

6. The method according to one of the claims 1 to 5, characterized in that the majority of the powder particles (1) have a diameter in the range of 10 to 100 μ.

7. The method according to one of the claims 1 to 6, characterized in that the evacuated interspaces (2) between the powder particles (1) comprise 25% to 35%, preferably between 26% to 30% of the total volume of the powder.

8. The method according to one of the claims 1 to 7, characterized in that the powder particles (1) are coated with a polymerization catalyst, preferably with a peroxide.

9. The method according to one of the claims 1 to 8, characterized in that additional components, preferably radioopaquers and/or antibiotics are used in a geometrically similar form to the powder particles (1).

10. Apparatus for carrying out the method according to one of the claims 1 to 9, characterized in that said apparatus comprises:

A. means (4) for confining the powder component (1) and maintaining it in an evacuated condition,

B. means (10;5,6) for introducing the liquid component (11), and

C. means (18,19;5,20) for expelling the two component cement mass (15) from said apparatus.

11. Apparatus defined in claim 10, characterized in that the means (4) for confining the evacuated powder component (1) are inflexible.

12. Apparatus according to one of the claims 10 or 11, characterized in that said apparatus comprises a syringe (4) with piston (5) and plug (6) and an internal mixing device (7), which preferably is collapsable axially with regard to the syringe longitudinal axis.

13. Means for performing the method according to one of the claims 1 to 9, characterized in that said means comprises an ampule (13) containing the liquid component (11) with two necks (26,27) at opposite ends of the ampule (13) for breaking-off and opening of said ampule (13), and preferably with a narrowed end (22) allowing for attachment of a needle (10).

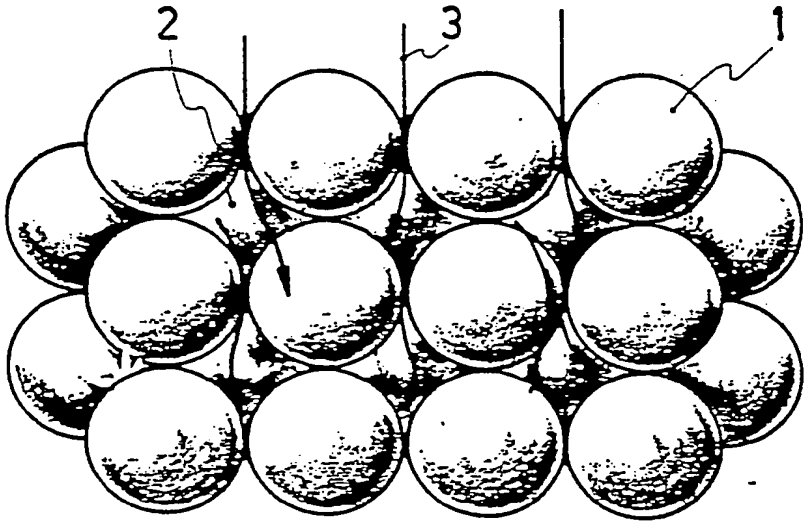


FIGURE 1

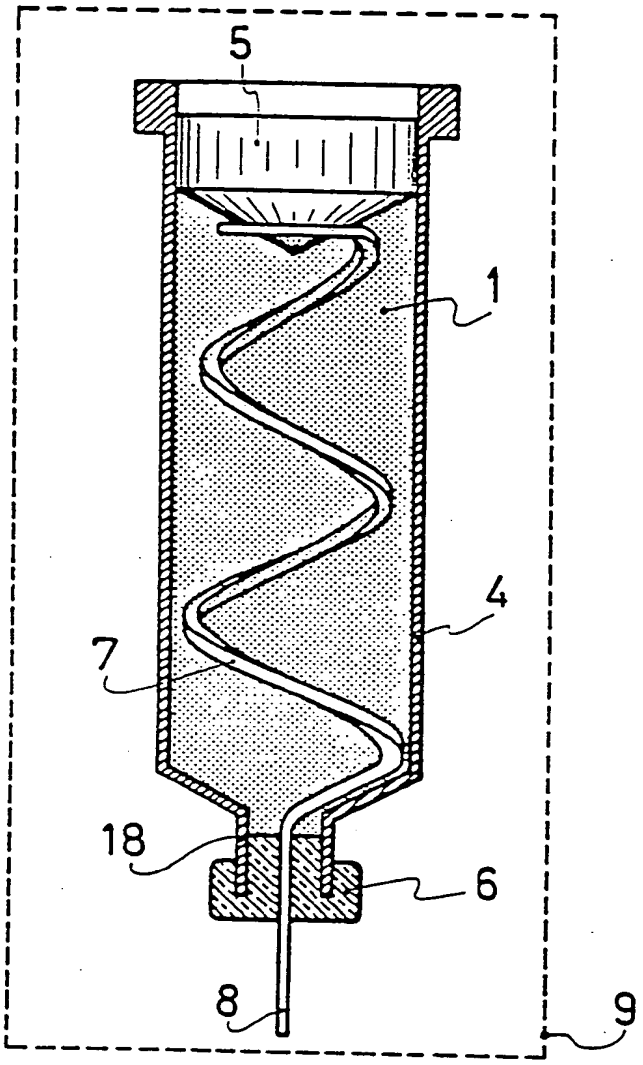


FIGURE 2

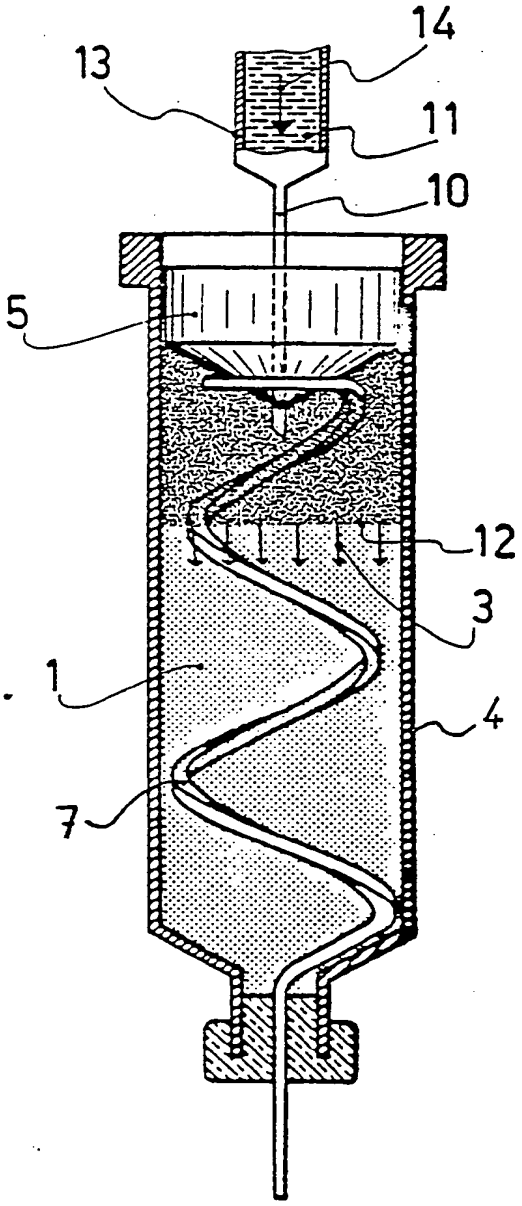


FIGURE 3

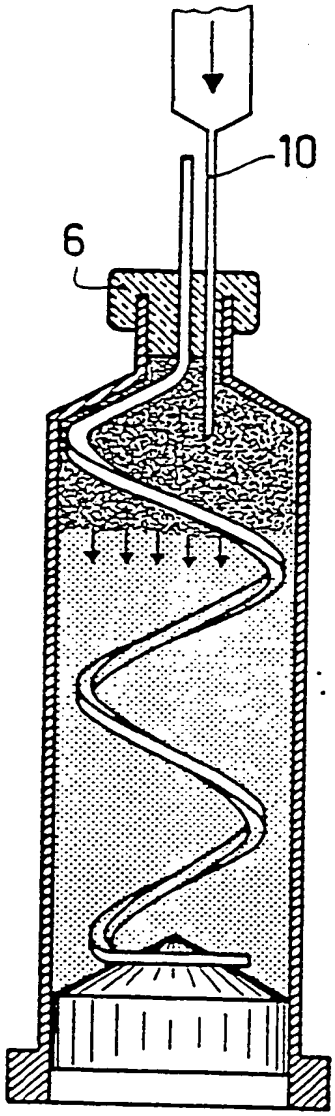


FIGURE 4

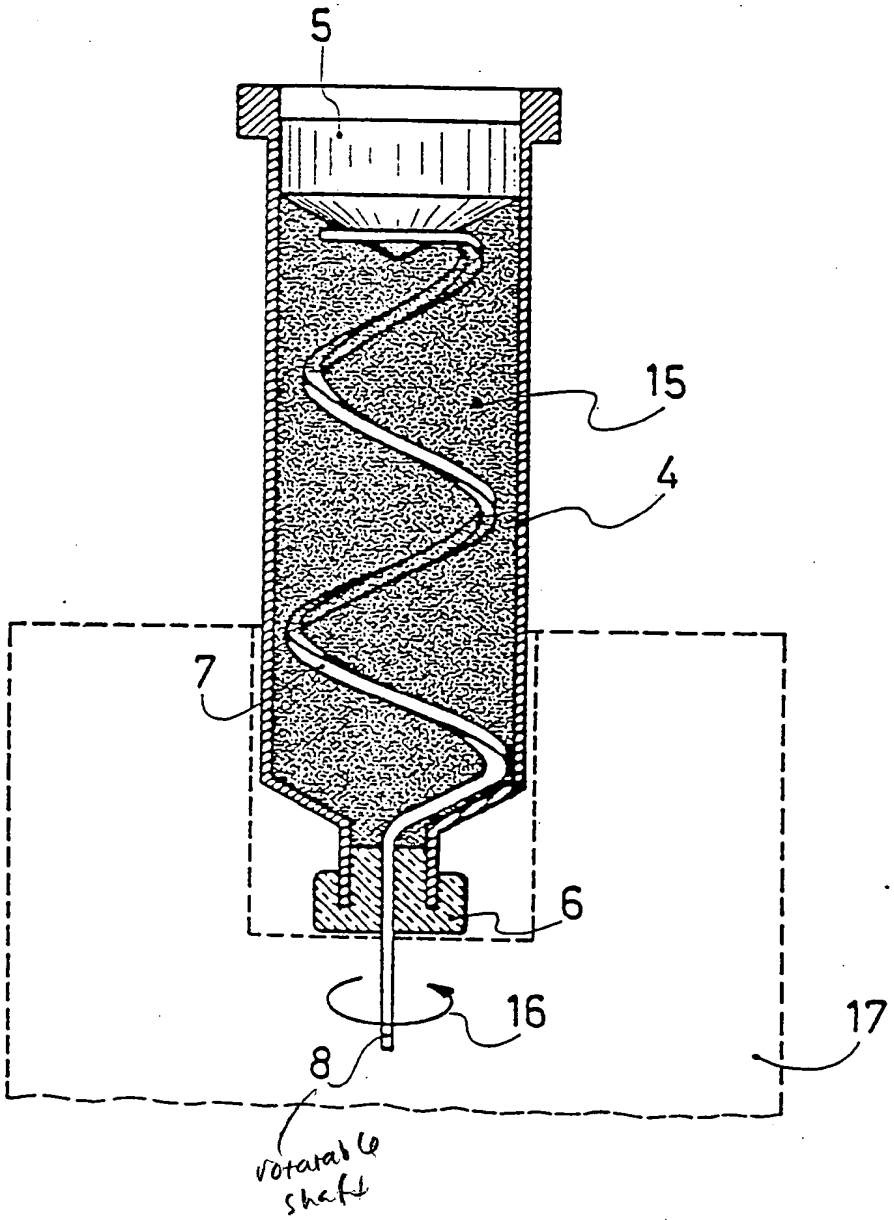


FIGURE 5

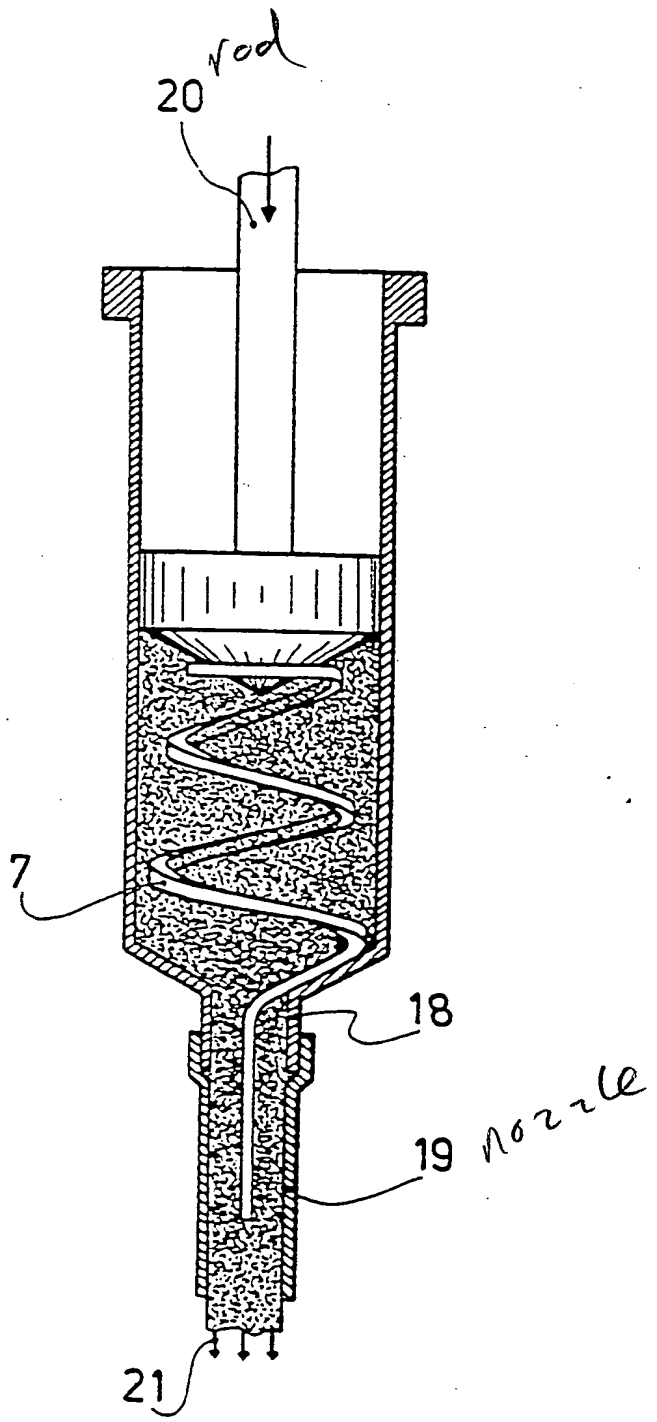


FIGURE 6

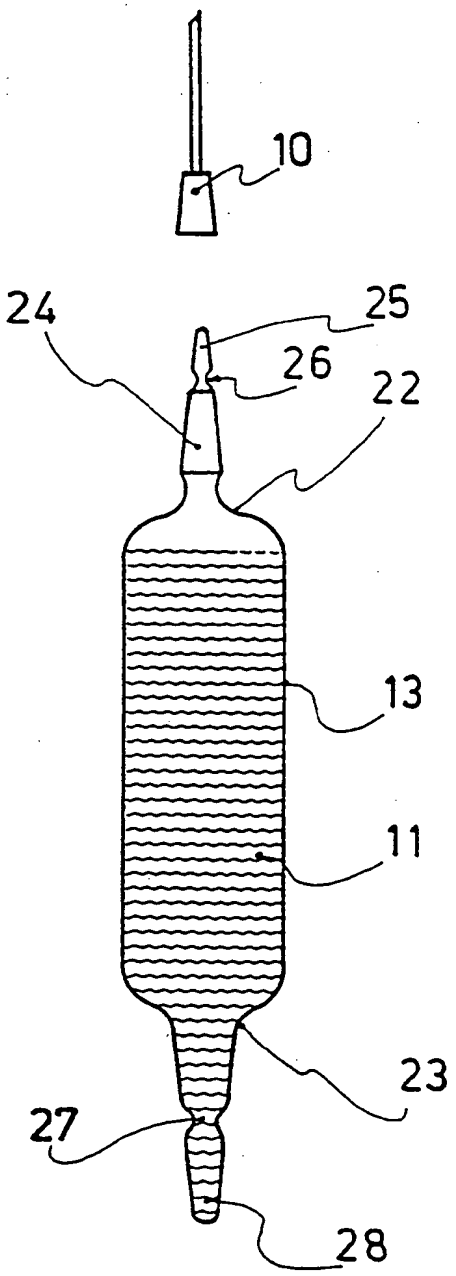


FIGURE 7

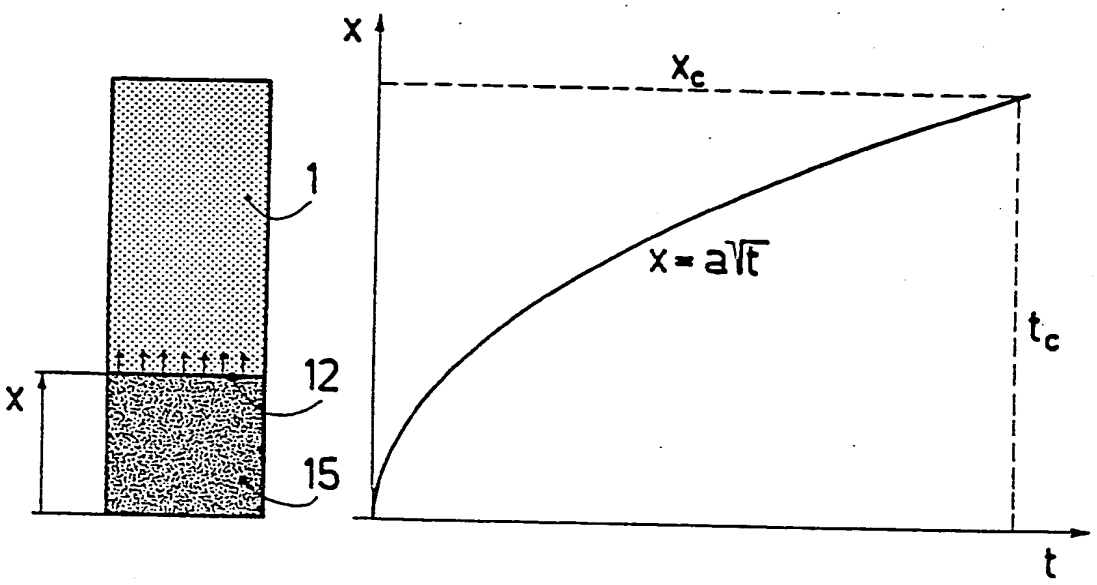


FIGURE 8

INTERNATIONAL SEARCH REPORT

International Application No PCT/EP 85/00227

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC[4]: A 61 F 2/46; A 61 F 2/30

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
IPC[4]	A 61 F A 61 M A 61 B A 61 L A 61 C

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
X Y	US, A, 4463875 (TEPIC) 7 August 1984, see column 6, lines 17-23,45-48	1-3 4,8-13
Y	DE, A, 2801706 (SULZER) 7 July 1979, see page 9, line 16 - page 10, line 5	4,10-13
Y	DE, B, 2229702 (SULZER) 13 December 1973, see column 2, lines 39-62	8,9
A	GB, A, 2069517 (ANUTA) 19 February 1981, see claim 1	1,3,6
A	FR, A, 2370468 (IMPERIAL CHEMICAL INDUSTRIES) 10 November 1977, see claims 6,7,11,12	1,3,6
A	GB, A, 2085461 (BONFIELD et al.) 28 April 1982, see page 1, lines 53-55	5
A	EP, A, 0061108 (EITENMULLER) 29 September 1982, see page 11, lines 13,14	1,3
A	US, A, 4141864 (RIJKE et al.) 27 February 1979, see column 3, lines 38-44; column 6	1,3 ./.

* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
13th January 1986	30 JAN. 1986
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	G.L.M. Kruydenberg

Form PCT/ISA/210 (second sheet) (January 1985)

International Application No. PCT/EP 85/00227

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FR M THE SECOND SHEET)

Category *	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No
A	US, A, 4185072 (PUDERBAUGH et al.) 22 January 1980, see column 2, line 66 - column 3, line 2	1
A	US, A, 2176042 (PITTENGER) 25 June 1936, see column 4, lines 54-61; figures	1,4,10,13

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON

INTERNATIONAL APPLICATION NO. PCT/EP 85/00227 (SA 9690)

This Annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 23/01/86

The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US-A- 4463875	07/08/84	WO-A-	8504567	24/10/85
DE-A- 2801706	12/07/79	AT-B-	357266	25/06/80
		CH-A-	622752	30/04/81
DE-B- 2229702	13/12/73	NL-A-	7209059	14/12/73
		FR-A,B	2187278	18/01/74
		BE-A-	800765	12/12/73
		CH-A-	564340	31/07/75
		GB-A-	1431211	07/04/76
		CA-A-	993588	20/07/76
		AT-B-	333973	27/12/76
GB-A- 2069517	26/08/81	FR-A-	2478461	25/09/81
		JP-A-	56131630	15/10/81
		DE-A-	3106452	07/01/82
		AU-A-	6742281	27/08/81
		US-A-	4341691	27/07/82
		CA-A-	1150880	26/07/83
		CH-A-	646721	14/12/84
FR-A- 2370468	09/06/78	DE-A,B,C	2750326	18/05/78
		US-A-	4174334	13/11/79
		GB-A-	1587904	15/04/81
GB-A- 2085461	28/04/82	EP-A-	0049720	21/04/82
EP-A- 0061108	29/09/82	DE-A-	3110681	30/09/82
		DE-A-	3134728	10/03/83
US-A- 4141864	27/02/79	None		
US-A- 4185072	22/01/80	CA-A-	1100940	12/05/81
US-A- 2176042		None		